REMARKS

Objection to the Specification

The Examiner objected to the specification on the basis that the word "cap" was used to describe the "pellet" or precipitate resulting from centrifugation. The word cap has been replaced with pellet throughout the specification.

Objections to Claims 36 and 61

The Examiner stated that, should Claim 36 be found allowable, Claim 61 would be objected to as being a substantial duplicate. Claim 61 has been deleted, and Claim 62 (previously dependent on Claim 61) has been amended to depend from Claim 36.

Objections to Claims 32 and 52

The Examiner further stated that, should Claim 32 be found allowable, Claim 52 would be objected to as being a substantial duplicate. Applicants respectfully traverse this objection.

Claim 28, to which Claim 32 depends, specifies that the active agent is capable of inactivating a macrolide, tetracycline or quinolone antibiotic. Claim 45, from which Claim 52 depends, only specifies that the active agent is capable of inactivating an antibiotic. Thus, Claim 32 is of substantially narrower scope than Claim 52, and thus these claims are not substantial duplicates.

Objection to Claim 14

Claim 14 was objected to as being of improper dependent form, purportedly on the basis that it did not require the selection of a macrolide antibiotic, only for a quinolone antibiotic. The

basis for this objection is not understood. Erythromycin is a macrolide antibiotic (http://www.rohmhaas.com/ionexchange/Pharmaceuticals/Erythromycin.htm). Claim 14 reads on Claim 13, which reads on Claim 12. Claims 12-14 are reproduced below:

12. (Original) A drug delivery device for oral administration, and colonic release, of an active agent, comprising:

a) an active agent capable of inactivating an antibiotic, and

b) a drug delivery device suitable for administering the active agent to the colon.

13. (Original) The drug delivery device of Claim 12, wherein the active agent is an enzyme capable of inactivating macrolide or quinolone antibiotics.

14. (Original) The drug delivery device of Claim 13, wherein the enzyme capable of inactivating macrolide antibiotics is erythromycin esterase.

Since Claim 13 relates to the inactivation of macrolide antibiotics, erythromycin is a macrolide antibiotic, and erythromycin esterase is an enzyme capable of inactivating erythromycin, it is unclear how there is not proper antecedent basis. However, if this objection is maintained, Applicants will simply amend Claim 14 to depend from Claim 12 and remove the word "macrolide" from the claim (since the word macrolide does not appear in Claim 12).

Rejections under 35 U.S.C. 101

Claims 12-14, 28-31, 36, 59-62, and 65 were rejected under 35 U.S.C. 101, as purportedly being directed to non-statutory subject matter, on the basis that they would be interpreted as comprising a product of nature, that is, E. coli, which inherently produces

erythromycin esterase, and is suitable for delivering the enzyme to the colon. Claims 36 and 59 are also directed to compositions that can deliver peptides, proteins, genes, and the like, which may be naturally-occurring, and as presently claimed, do not require isolation, purification or other manipulation which would free the compositions from naturally-occurring materials/products/combinations.

Claims 12, 28, and 59 have been amended to specify that the active agent is in isolated form. It is believed that this amendment obviates the rejections.

Rejections under 35 U.S.C 112, First Paragraph

Claim 65 was rejected under 35 U.S.C 112, first paragraph, as non-enabled. The basis for the rejection is that the claims relate to the treatment of ulcerative colitis and Crohn's disease, and the Examiner believes that only the symptoms of these diseases are being treated, not the diseases themselves.

A quick search on google.com reveals 109,000 hits related to the treatment of ulcerative colitis. A brief review of the first several hits shows discussions by the Mayo Clinic and others related to the treatment of ulcerative colitis. If the Mayo Clinic knows what is meant by the treatment of ulcerative colitis, and does not refer to it as "treating the symptoms of ulcerative colitis," Applicants respectfully suggest that the claims are enabled. However, if the rejection is maintained, Applicants reserve the right to amend the claims as suggested by the Examiner.

Rejections under 35 U.S.C. 102 (b)

Claims 12-14, 28-31, 36, 59-62, and 65 were rejected under 35 U.S.C. 102 (b) as anticipated by U.S. Patent No. 6,500,423 to Olshenitsky, as evidenced by Arthur, Annales de l'Institut Pasteur, Microbiologie 137(1.1) Jan/Feb 1986, pages 125-134 and Ounissi and Courvalin, P. Gene 1985, 35(3), pages 271-278.

Olshenitski purportedly teaches a composition comprising an active agent (a probiotic) and a drug delivery device. The secondary references were cited to show that probiotics (bacteria) inherently produce agents that might contain/produce erythromycin esterase.

The claims have been amended to specify that the active agent capable of inactivating antibiotics is in isolated form, and each of the working examples shows the use of isolated beta-lactamase and erythromycin esterase.

Olshenitski therefore does not teach or suggest each element of the claims.

The isolated enzymes offer advantages over the use of the bacteria themselves. For example, the enzymes themselves present no risk of bacterial infection, in contrast to administering the bacteria itself to the colon. Further, there is no risk of transferring bacterial resistance from the bacteria which produce the enzymes to bacteria already present in the gut that do not produce such enzymes.

The isolated enzymes offer disadvantges over the use of the bacteria themselves. As isolated peptides/proteins, they are more susceptible to degradation when administered in the oral route than the bacteria themselves.

Thus, it would not even be obvious from the teachings of Olshenitski to deliver the isolated enzymes.

Rejections under 35 U.S.C. 103 (a)

Claims 12-18, 28-36, 45-55, and 59-65 were rejected under 35 U.S.C. 103 (a) as obvious over Sriamoransak, Munjeri, Noguchi, and Ounissi.

Sriamoransak and Munjeri purportedly teach active agents and pectinate beads. Noguchi and Ouinissi teach proteins, including isolates of the enzymes erythromycin esterase and macrolide 2'-phosphotransferase I (Mph(A), which are capable of inactivating antibiotics. The purported basis for the rejection is that the claims are a mere combination of old elements, by enclosing the active agent into the pectinate bead.

A significant amount of research has been conducted to identify enzymes capable of inactivating antibiotics. The primary reasons for conducting the research have been to identify ways to deliver antibiotics that are resistant to these enzymes, or to identify agents that inactivate such enzymes (i.e., clavulanic acid and its salts).

For example, many bacteria have become resistant to beta-lactam containing antibiotics, by developing beta-lactamase enzymes. To counter this resistance, clavulanic acid or its salts, which inactivate the beta-lactamase enzymes, have been administered in combination with the antibiotics.

The reason the authors in the cited references focused on identifying these enzymes has been to counter bacterial resistance. Accordingly, it would not be obvious to purposefully administer the enzymes to the colon, as required by the claims, to minimize the concentration of antibiotics in the colon.

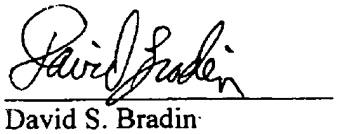
This situation is analogous to the identification of snake venom. Efforts have been made to identify the structure of various snake venoms in order to provide a cure for snakebites. However, absent some other motivation, the use of snake venom or its derivatives to treat thrombosis would not have been obvious merely because the structure of the venom had been characterized. Similarly, the use of isolated enzymes that inactivate antibiotics to reduce antibiotic concentrations in the colon is not obvious merely because the structure of certain enzymes has been determined.

For at least this reason, the rejection should be withdrawn.

Conclusion

It is believed that the claims are currently in condition for allowance. The Examiner is encouraged to contact Applicants' undersigned representative if he has any questions regarding the above.

Respectfully submitted,



David S. Bradin
Reg. No. 37,783
Attorney for Applicant

Intellectual Property Technology Law, PLLC
PO Box 14329
Research Triangle Park, NC 27709
USA
Telephone: (919) 419-9350
Facsimile: (919) 419-9354

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